

DEPARTMENT OF HEALTH AND HUMAN SERVICES

April 13, 1999

Dr. Roland Franz  
Fraunhofer Institut Verfahrenstechnik und Verpackung  
Giggenhauser Straße 35  
D-85354 Freising  
Germany

Dear Dr. Franz:

This responds to your submission of May 28, 1998, on behalf of OHL Apparatebau & Verfahrenstechnik GmbH (OHL), requesting FDA's opinion on the regulatory status of post-consumer recycled (PCR) polyethylene terephthalate (PET) flake produced by \_\_\_\_\_ for further use to manufacture articles intended to contact food. Your submission states that the source of the PCR-PET will be "food grade" PET complying with 21 CFR 177.1630 obtained from collected soda bottles.

We have reviewed your information submitted to demonstrate the capability of \_\_\_\_\_ to remove potential contaminants from PCR-PET. You have provided analytical data and results from diffusion modeling on surrogate contaminants intentionally added to PET to represent contaminated post-consumer feed material.

Based on our review of these data, we conclude that the levels of exposure to possible contaminants resulting from the proposed use of PCR-PET that was subjected to the process described in your submission would be below FDA's threshold of regulatory concern. Therefore, we conclude that the recycling process described in your submission will produce PCR-PET that is acceptable for use in contact with food at room temperature or lower, provided the PCR-PET complies with 21 CFR 177.1630, and any other applicable regulations. Although your request did not specify the types of food that the PCR-PET will contact or the maximum temperature of use of the PCR-PET, based on the conditions used in the extraction studies, we are limiting the use of the PCR-PET for contact with all types of food at room temperature (120°F) and below. Our conclusion applies only to post-consumer PET collected and processed as described in your May 28, 1998, submission. If your recycling process is modified, new data would need to be evaluated.

Although we have concluded that the intended use of PCR-PET that has been collected and processed in the manner described in your submission is acceptable, you should be aware that we are currently developing a formal policy on the use of post-consumer recycled plastics in contact with food. Thus, the decisions set forth in this letter may need to be modified due to future deliberations on this matter.

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Page 2 - Dr. Franz

If you have any further questions concerning this matter, please do not hesitate to contact us.

Sincerely,

A handwritten signature in black ink, appearing to be 'EC Coleman', written over a horizontal line.

Eugene C. Coleman  
Director,  
Division of Petition Control, HFS-215  
Center for Food Safety  
and Applied Nutrition